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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,730	12/19/2000	Allan F. Willis	KCX-332 (15927)	5590

7590 05/16/2003

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EXAMINER
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GHAFOORIAN, ROZ

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 05/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/741,730

Applicant(s)

WILLIS ET AL.

Examiner

Roz Ghafoorian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 April 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 and 23-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 23-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

1. Claims 1, 3-7, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Patent No.5997503 to Willis et al, and further in view of Patent No.6050934 to Mikhail et al.

Willis teaches a catheter with distally distending balloon. Willis's apparatus is a gastrostomy catheter which comprises of a valve housing defining an opening having a central axis, the opening extending through the valve housing such that the opening forms part of the fluid path through the medical product. It further contains a valve member disposed within the opening, the valve member having a single seal interface defined by at least two opposing flexible walls biased towards each other to a sealing position, the valve member having a peripheral portion with the opposing flexible walls extending from the peripheral portion towards the central axis, the opposing flexible walls including ends that contract each other along the single seal interface. Willis, however, does not disclose any information regarding the degree of durometers in the material used to make the valve member. Mikhail discloses a urinary catheter having a palpatable discharge valve with protective shoulders. Mikhail teaches an anti-reflux valve with a valve member made of silicon rubber or other flexible polymeric materials such as Kraton and the like, and preferably having a durometer value of about 12 to about 95 shores. (Col.9, lines 25-30)

Therefore it could have been obvious to one having ordinary skill in the art at the time the invention was made to combine the two teachings, because according to Mikhail

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by making the valve wall and the valve member form a flexible polymeric material, the valve member can be deformed such that the valve opening can be opened from a closed position when sufficient force is applied to the valve wall to deform the valve member, wherein the valve opening will generally return to the closed position from the open position when the force is no longer applied. (Col. 4, lines 55-60)

2. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5997503 to Willis et al, and further in view of U.S. Patent Publication No. 0049501 to Osbourne et al or U.S. Patent No. 5720734 to Copenhaver et al. Willis teaches a catheter with distally distending balloon. Willis's apparatus is a gastrostomy catheter which comprises of a valve housing defining an opening having a central axis, the opening extending through the valve housing such that the opening forms part of the fluid path through the medical product. It further contains a valve member disposed within the opening, the valve member having a single seal interface defined by at least two opposing flexible walls biased towards each other to a sealing position, the valve member having a peripheral portion with the opposing flexible walls extending from the peripheral portion towards the central axis, the opposing flexible walls including ends that contract each other along the single seal interface. Willis, however, does not disclose any information regarding the thickness of the valve member, however the idea of using a thickness between 0.002 inches to 0.064 inches is well known in the art, the majority of the valve members are within the thickness

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mentioned above. Copenhaver and Osbourne are just two examples of apparatus with valve members that use thickness between 0.002 inches to 0.064 inches.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have used a thickness of 0.004 inches for the thickness of the valve member; because the valve members are used to be opened and closed depending on the exterior force placed on the valve and it is important to have the valve thick enough so it does not tear and thin enough so it does respond to the external force.

### ***Allowable Subject Matter***

3. Claims 23-27 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: the applicant has claimed a valve member having a single seal interface with two opposing flexible walls; the two opposing flexible walls include material having two different durometers.

### ***Response to Arguments***

4. Applicant's arguments filed 4-28-2003 have been fully considered but they are not persuasive:

a. The applicant has argued that Mikhail 934 does not teach a durometer of less than about 12, however Mikhail 934 teaches a durometer about 12 shores.

The term about is very broad and hence it does cover less than 12 shores as the applicant has claimed.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Ghafoorian whose telephone number is 703-305-2336. The examiner can normally be reached on 8:30am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

RG  
May 7, 2003



**MICHAEL J. HAYES  
PRIMARY EXAMINER**